Conceptual Framework for Biosecurity Levels

Jennifer Gaudioso and Reynolds Salerno
Sandia National Laboratories

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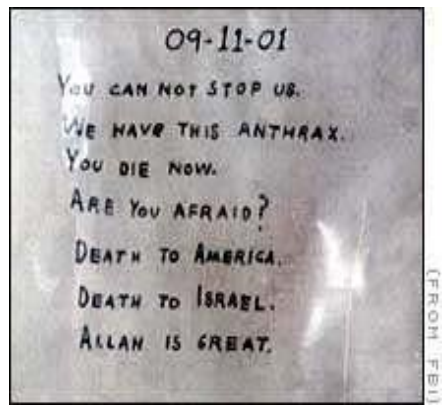
Need to Secure Certain Pathogens and Toxins

- **Aim of biosecurity is to mitigate biological weapons (BW) threat at the source**
  - Prevent terrorists or proliferant states from acquiring biological agents from government, commercial, or academic facilities
- **Biosecurity only addresses a small part of the BW threat**
  - Biosecurity cannot prevent BW terrorism or proliferation, or even diversion
  - Biosecurity should be designed to deter and detect theft or sabotage
- **Research community needs specific tools to achieve a balance between**
  - Adequately protecting certain pathogens and toxins
  - Not jeopardizing research on those agents and toxins



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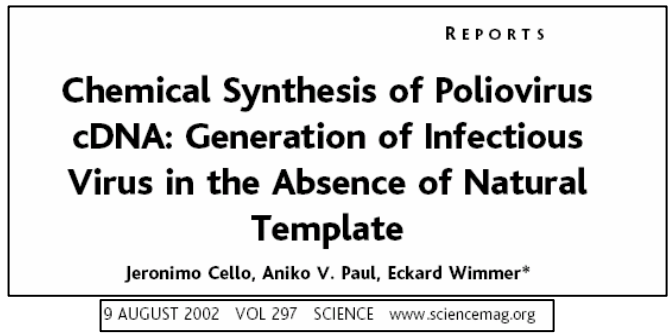
Bioscience Research and Security

- **Top-down security regime**
- **No need to acquire biological material from a bioscience facility to pursue bioterrorism**
- **Nature of the material makes diversion extremely difficult to prevent**
- **Dual-use characteristics of biological materials and technology make identification of illegitimate activities extremely difficult**
- **Control of certain biological materials is necessary**
  - But *how* that is achieved must be carefully considered and implemented

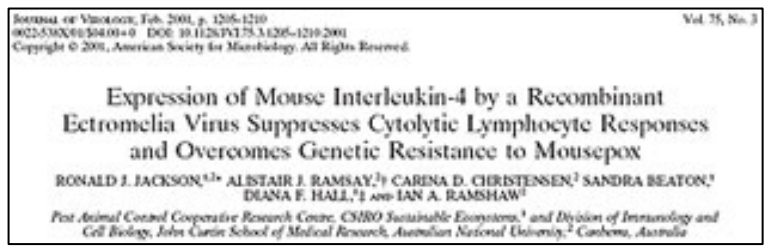


REPORTS

Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template

Jeronimo Cello, Aniko V. Paul, Eckard Wimmer*

9 AUGUST 2002 VOL 297 SCIENCE www.sciencemag.org



JOURNAL OF VIROLOGY, Feb. 2001, p. 1205–1210 Vol. 75, No. 3
0022-538X/01/$04.00+0 DOI: 10.1128/JVI.75.3.1205–1210.2001
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Expression of Mouse Interleukin-4 by a Recombinant Ectromelia Virus Suppresses Cytolytic Lymphocyte Responses and Overcomes Genetic Resistance to Mousepox

RONALD J. JACKSON,[1,2]* ALISTAIR J. RAMSAY,[2]† CARINA D. CHRISTENSEN,[2] SANDRA BEATON,[1] DIANA F. HALL,[1]‡ AND IAN A. RAMSHAW[2]

Post Animal Council Cooperative Research Centre, CSIRO Sustainable Ecosystems,[1] and Division of Immunology and Cell Biology, John Curtin School of Medical Research, Australian National University,[2] Canberra, Australia

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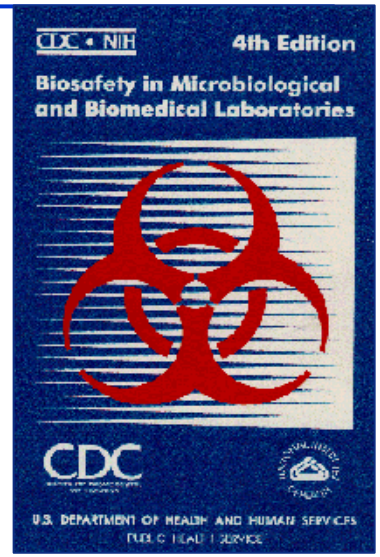
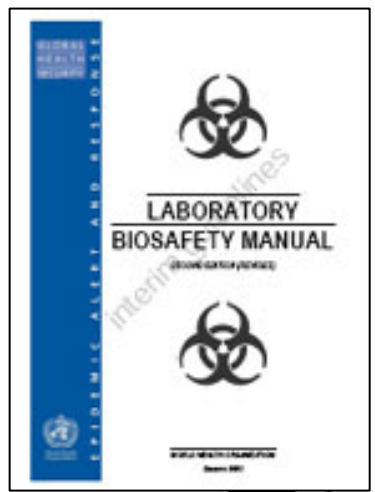
Biosafety as a Model

- **Biosafety aims to reduce or eliminate accidental exposure to or release of hazardous agents**
  - CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories” (BMBL)
  - WHO “Laboratory Biosafety Manual” (LBM)
- **Four biosafety levels**
  - Graded application of practices and techniques, laboratory equipment, and facility design (“containment”)
  - Based on agent safety risk assessments
- **Biosafety now considered standard microbiological practice around the world**





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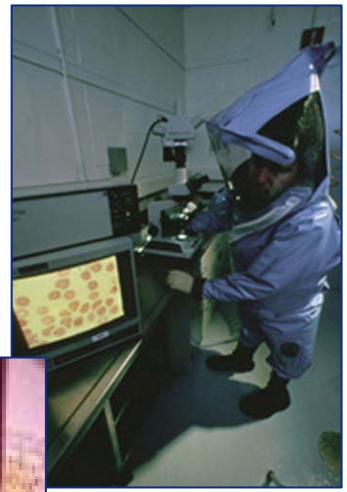
Risk Management for Biosecurity

- **Need to appreciate that risk will always exist**
  - Every asset cannot be protected against every conceivable threat
  - Distinguish between “acceptable” and “unacceptable” risks
- **Employ a risk management approach**
  - Conduct an asset-based security risk assessment
  - Ensure that the amount of protection provided to a specific asset, and the cost for that protection, is proportional to the risk of the theft or sabotage of that asset



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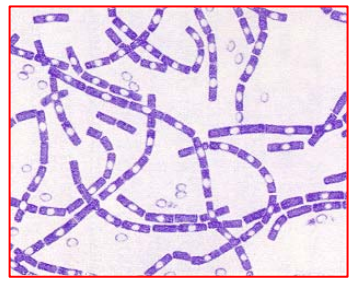
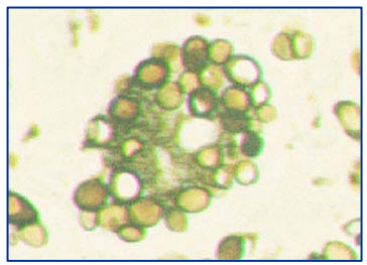
Biological Agent Security Risk Assessment

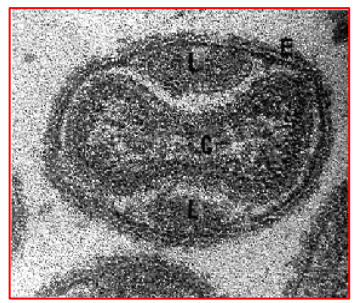
- **All pathogens and toxins do not need the same level of protection**
- **Agents should be placed in a Biosecurity Level based upon their risk of theft and use as a biological weapon**
  - Risk should be a function of both weaponization potential and consequences of use
- **Weaponization potential is the ease or difficulty that an agent may be deployed maliciously**
- **Consequences of use are associated with the infectious disease characteristics of the agent**



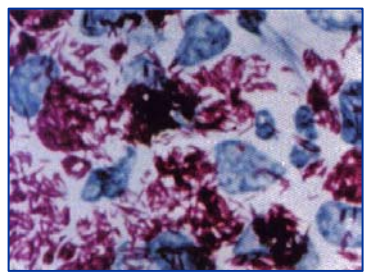
Bacillus anthracis



Coccidioides immitis



Variola major



Mycobacterium leprae

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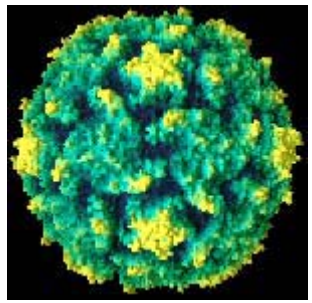
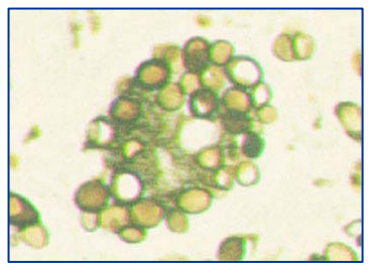
Biological Agent Security Risk Levels

- **Nonpathogenic**
  - Malicious use would have insignificant or no consequences
- **Low Risk Pathogens and Toxins (LRPT)**
  - Difficult to deploy maliciously, and/or
  - Malicious use would have few consequences
- **Moderate Risk Pathogens and Toxins (MRPT)**
  - Relatively difficult to deploy maliciously, and
  - Malicious use would have localized consequences with low to moderate casualties and/or economic damage
- **High Risk Pathogens and Toxins (HRPT)**
  - Not particularly difficult to deploy maliciously, and
  - Malicious use could have national or international consequences, causing moderate to high casualties and/or economic damage
- **Extreme Risk Pathogens and Toxins (ERPT)**
  - Would normally be classified as HRPT, except that they are not found in nature (eradicated)
  - Could include genetically engineered agents, if they were suspected of being a HRPT



MRPT Agent Example: *Coccidioides immitis*

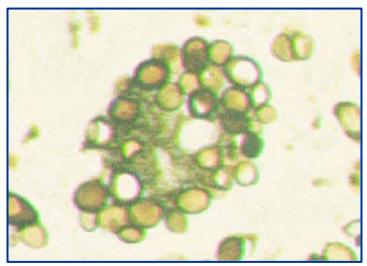
- **Consequences**
  - Coccidioidomycosis (Valley fever)
    - Usually asymptomatic, 30-40% of infected become ill
    - Not contagious
    - 5-10 out of every 1000 infected develop life-threatening infection
- **Weaponization potential**
  - Requires technical skills to handle
  - Easy to procure virulent strain (wide endemic area)
  - Easy to grow colonies and produce spores
- **Conclusion: low to moderate consequences and moderate weaponization potential**



Coccidioides immitis

Moderate Risk Security Level

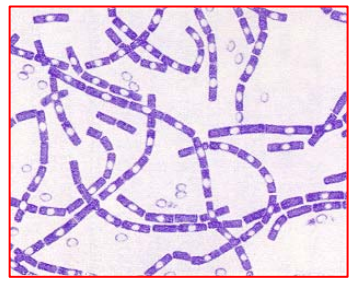
- Basic access controls (e.g. controlled keys) for areas where agents are used and stored
- Basic personnel suitability check should be completed for all those who enter the controlled area
- Materials should be accounted for and inventoried in databases



Coccidioides immitis

HRPT Agent Example: *Bacillus anthracis*

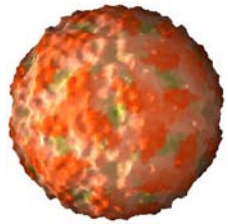
- **Consequences**
  - Pulmonary anthrax (via aerosolized anthrax)
    - High fatality rate
    - Not contagious, relatively high infectious dose required
    - Early diagnosis is difficult
- **Weaponization potential**
  - History of weaponization and terrorist use
  - Wide endemic area but many less virulent strains
  - Easy to grow colonies and produce spores
  - Very stable in environment and storage
- **Conclusion: moderate to high consequences and relatively high weaponization potential**



Bacillus anthracis

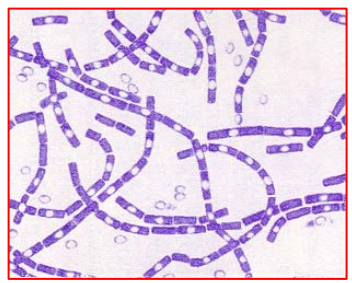
High Risk Security Levels

- Electronic access controls
- Personnel screening should include more comprehensive background investigations
- Accountability records should be maintained
- Material transfers should be pre-approved and require a continuous chain of custody
- Information about the security of these agents should be protected
- Biosecurity Officer should oversee the implementation of appropriate biosecurity measures



FMD virus

Yersinia pestis



Bacillus anthracis

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Result of a Biosecurity-Level System

- **Most pathogens and toxins would likely be LRPT**
- **Most current Select Agents would likely be MRPT**
- **Security associated with LRPT and MRPT would be achievable at reasonable cost for the broad biological research community**
  - Rely largely on existing biosafety measures

- **Very few Select Agents would be HRPT or ERPT**
- **Security for facilities that work with HRPT or ERPT would be relatively significant, but should still**
  - Rely largely on policies and procedures
  - Be transparent to the users
  - Use resources efficiently
  - Not unnecessarily hinder normal operations (e.g. research, diagnostics, biosafety)

Summary

- Necessary to take steps to reduce the likelihood that certain pathogens and toxins could be stolen from bioscience facilities
- Biosecurity should be applied in a graded manner, ensuring that the amount of protection provided to a specific agent is proportional to the risk of the theft or sabotage of that agent
- Critical that biosecurity systems are designed specifically for biological materials and research so that the resulting system will balance science and security concerns
- Biosecurity measures should reinforce and complement existing biosafety measures
- Need to involve scientific community in development of agent-based security risk assessments and biosecurity standards to build essential understanding and acceptance

Contact Information

Sandia National Laboratories
PO Box 5800, MS 1371
Albuquerque, NM 87185
USA

Jen Gaudioso – Tel. 505-284-9489 email jmgaudi@sandia.gov
Ren Salerno – Tel. 505-844-8971 email rmsaler@sandia.gov

www.biosecurity.sandia.gov

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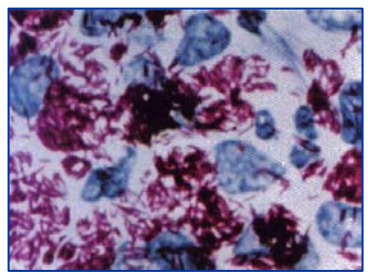
LRPT Agent Example: *Mycobacterium leprae*

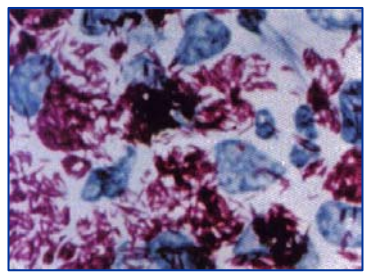
- **Consequences**
  - Leprosy
    - Not highly virulent, most exposed people do not develop leprosy
    - Not highly contagious
    - Completely curable – majority recover without treatment
- **Weaponization potential**
  - Production is a significant challenge
  - Not environmentally hardy
- **Conclusion: low consequences and low weaponization potential**



Mycobacterium leprae

Low Risk Security Level

- Doors on unattended laboratories should be locked
- Principal Investigator should be aware of work and individuals in his/her lab
- Laboratory notebooks should document the stocks and use of agents

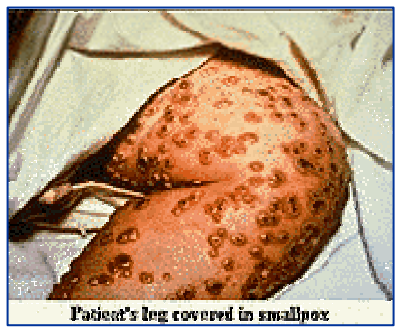


Mycobacterium leprae

ERPT Agent Example: Variola major virus

- **Consequences**
  - Smallpox
    - High fatality rate
    - Contagious
    - Very few people vaccinated
- **Weaponization potential**
  - History of weaponization
  - Very stable in aerosol
  - Extremely difficult to obtain
- **Conclusion: high consequences and moderate weaponization potential**

Variola major



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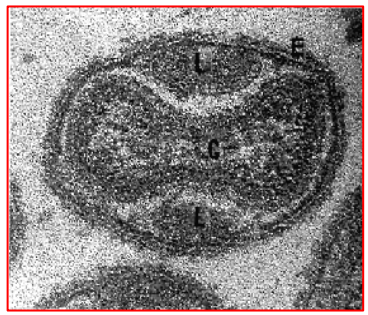
Extreme Risk Security Level

- Two- or three-level electronic access controls
- In-depth personnel suitability background checks
- Accountability records should be maintained
- Two authorized individuals should be required for access to repository stocks
- Material transfers should be pre-approved and require a continuous chain of custody
- Information about the security of these agents should be protected
- Local guard force should be able to respond to intrusions
- Biosecurity Officer should oversee the implementation of appropriate biosecurity measures



Variola major

Patient's leg covered in smallpox